

The Defendant, Alaunus Pharmaceutical, LLC (“Alaunus”), by and through its counsel, hereby moves the Court to dismiss the amended complaint for failure to state a claim upon which relief may be granted pursuant to Fed. R. Civ. P. 12(b)(6).

The amended complaint, which purports to be a class action products liability suit filed by Plaintiffs Lance Martin (“Mr. Martin”) and Toby Martin (“Mrs. Martin”), husband and wife, on behalf of themselves and all others similarly situated, asserts claims of negligence, breach of express warranty, breach of the implied warranty of merchantability, breach of implied warranty of fitness for a particular purpose, and loss of consortium,¹ collectively against New England Compounding Pharmacy, Inc. (“NECC”), Ameridose, LLC (“Ameridose”), and Alaunus. The

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claims arise out of alleged injuries suffered by Mr. Martin from an injection of a steroid compound that Plaintiffs suspect were contaminated with a fungal agent. Plaintiffs assert that the steroid compound was manufactured or distributed by the Defendants. The complaint should be dismissed pursuant to Rule 12(b)(6) because: (1) it fails to allege sufficient factual allegations to show that Mr. Martin has a plausible right to recovery against Alaunus under any of the theories of liability asserted by the Plaintiffs; (2) it fails to allege a legally sufficient injury as to Mr. Martin; and, (3) Mrs. Martin is not entitled to any recovery for loss of consortium since her claim is derived from Mr. Martin's failed claims.

II. FACTUAL ALLEGATIONS IN THE AMENDED COMPLAINT

The amended complaint alleges, in relevant part, that Mr. Martin received an injection of Methylprednisone Acetate Product (MAP), a prescription steroidal medication which is compounded and provided in liquid form thereby requiring an injection for administration, from Greenspring Surgery Center, 2700 Quarry Lake Drive, Baltimore, MD 21209 on September 10, 2012. Amended Compl. ¶ 18. The complaint alleges that the FDA issued a recall notice to the members of the public that "NECC had distributed several lots of [MAP] that had been placed in commerce by NECC were contaminated with *Aspergillus* fungus and/or other contaminants," *id.* at ¶ 19, and that Mr. Martin "was notified by Greenspring Surgery Center that he was exposed to the Defendants' contaminated [MAP]," *id.* at 23. The complaint alleges that MAP has been distributed throughout the United States, *id.* at 20, and that 18,000 vials of MAP, which were placed in interstate commerce by NECC and Ameridose were subject to the recall, *id.* at 21. As a result of his suspected exposure to a contaminated MAP injection, the Plaintiffs claim that Mr. Martin has suffered emotional distress and requires medical monitoring of his condition because he is at risk for developing fungal spinal meningitis. *Id.* at 26, 27.

The factual allegations in the complaint regarding Alaunus are scant and are predominantly made upon information and belief. The complaint alleges that Alaunus' resident agent for the

service of process is Gregory Conigliaro, *id.* at 7, and that NECC, Alaunus and Ameridose share common officers and managers, including Gregory Conigliaro and Barry Cadden, *id.* at 12. *Upon information and belief*, the complaint alleges that NECC, Ameridose and Alaunus: shared facilities and/or employees in the sale and distribution of various regulated drug and pharmaceutical compounds, including but not limited to, MAP, *id.* at 11; shared common employees and pharmacists in their operations, including the manufacture, distribution and sale of various compounded products and medications, *id.* at 12; jointly participated in the development, sale, marketing and distribution of compounded medications and products throughout several states within the United States, *id.* at 13. The complaint also asserts *upon information and belief* that Ameridose and/or Alaunus: supplied NECC with various components of compounded medications for use and sale in compounded products, *id.* at 14; actively supported and supervised NECC in its business activities, including the production, compounding, testing, inspecting, marketing, sale and distribution of compounded products, *id.* at 14; and, actively participated in NECC production activities including but not limited to supervising, supporting, assisting, compounding, manufacturing, selling and distributing various compounded products such as Methylprednisone Acetate, *id.* at 15. Based upon those allegations which are made *upon information and belief*, Plaintiffs conclude that Alaunus, in conjunction with NECC and Ameridose: is engaged in the business of distributing various drug and pharmaceutical compounds including MAP throughout the United States, *id.* at 10; and, distributed MAP into the stream of commerce which was contaminated with *Aspergillus* and other fungal contaminants and agents which were capable of causing spinal meningitis, *id.* at 16.

III. DISCUSSION

The complaint should be dismissed pursuant to Rule 12(b)(6) because: (1) it fails to allege sufficient factual allegations to show that Mr. Martin has a plausible right to recovery against Alaunus under any of the theories of liability asserted in the complaint; (2) it fails to allege a

legally sufficient injury as to Mr. Martin; and, (3) Mrs. Martin is not entitled to any recovery for loss of consortium since her claim is derived from Mr. Martin's failed claims.

1. The amended complaint fails to allege sufficient factual allegations, as opposed to conclusory assertions, to show that Mr. Martin has a plausible right to recovery against Alaunus under any of the theories of liability asserted in the complaint.

To survive a motion to dismiss under Fed.R.Civ.P. 12(b)(6), the factual allegations in a complaint must "possess enough heft" to set forth "a plausible entitlement to relief." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544 (2007). To have facial plausibility, the complaint must contain "factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). The *Twombly-Iqbal* plausibility standard implicates a two-step analysis. *Grajales v. Puerto Rico Ports Authority*, 682 F.3d 40, 44 (2012), citing *Iqbal*, 556 U.S. at 678 - 679. First, "the court must separate the complaint's factual allegations (which must be accepted as true) from its conclusory legal allegations (which need not be credited)." *Grajales*, 682 F.3d at 44, citing *Morales-Cruz v. Univ. of P.R.*, 676 F.3d 220, 224 (1st Cir.2012). Second, the court must determine whether the factual content permits "the reasonable inference that the defendant is liable for the misconduct alleged." *Grajales*, 682 F.3d at 44 (internal quotation marks omitted), citing *Sepúlveda-Villarini v. Dep't of Educ. of P.R.*, 628 F.3d 25, 29 (1st Cir.2010) (Souter, J.) ("The make-or-break standard ... is that the combined allegations, taken as true, must state a plausible, not a merely conceivable, case for relief"). "If the factual allegations in the complaint are too meager, vague, or conclusory to remove the possibility of relief from the realm of mere conjecture, the complaint is open to dismissal." *Plumbers' Union Local No. 12 Pension Fund v. Nomura Asset Acceptance Corp.*, 632 F.3d 762, 771 (1st Cir. 2011).

- a. Other than the facts that Alaunus shared the same registered agent for service of process and the same officers and managers, all of the other allegations concerning Alaunus are conclusory assertions which should be disregarded by the court.

The allegations that Alaunus is “engaged in interstate commerce throughout the United States and provide(s) products and services, in the sale and distribution of various drug and pharmaceutical compounds, including Methylprednisone Acetate,” *Compl.* ¶10, and that Alaunus, in conjunction with NECC, distributed Methylprednisone Acetate in vials that were contaminated with a fungal agent capable of producing and causing spinal meningitis, *Compl.* ¶16, along with all of the other allegations which were made upon information and belief as to Alaunus are conclusory assertions which should be disregarded by the court.

On a motion to dismiss, “a plaintiff’s obligation to provide the ‘grounds’ of [her] ‘entitle[ment] to relief’ requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do.” *Twombly*, 127 S.Ct. at 1965. Naked assertions devoid of further factual enhancement need not be accepted. *Maldonado v. Fontanes*, 568 F.3d 263, 266 (1st Cir. 2009).² “Conclusions” only become “facts” for pleading purposes when “conclusions are logically compelled, or at least supported, by the stated facts,” as well as the reasonable inferences drawn therefrom. *The Dartmouth Review v. Dartmouth College*, 889 F.2d 13, 16 (1st Cir. 1989).

While the *Twombly-Iqbal* plausibility standard does not prevent a plaintiff from pleading facts alleged ‘upon information and belief’ where the facts are peculiarly within the possession and control of the defendant, *see, e.g., Boykin v. KeyCorp.*, 521 F.3d 202, 215 (2d Cir. 2008), or where the belief is based on factual information that makes the inference of culpability plausible, *see Iqbal*, 129 S. Ct. at 1949,” a plaintiff does not make a showing of a plausible entitlement to relief

² *See also Barrington Cove Ltd. Partnership v. Rhode Island Housing and Mortg. Finance Corp.*, 246 F.3d 1 (1st Cir.2001) (ruling that the court should not credit “conclusory assertions, subjective characterizations, or outright vituperation”); *Aulson v. Blanchard*, 83 F.3d 1, 3 (1st Cir. 1996) (stating that the court is not obligated “to swallow the plaintiff’s invective hook, line, and sinker; bald assertions, unsupportable conclusions, periphrastic circumlocutions, and the like need not be credited”).

simply by reciting a formula of facts “upon information and belief” regarding each of the elements of a cause of action. When a plaintiff alleges a fact “upon information and belief,” the assertion signifies that the “allegations are based on secondhand information that [the asserting party] believes to be true.” *Pirelli Armstrong Tire Corp. Retiree Med.Benefits Trust v. Walgreen Co.*, 631 F.3d 436, 442 (7th Cir. 2011) (quoting Black’s Law Dictionary 783 (7th ed. 1999); *Zuk v. E. Pa. Psychiatric Inst. of the Med.Coll. of Pa.*, 103 F.3d 294, 299 (3d Cir. 1996). In the absence of factual allegations of secondhand information that the plaintiff believes to be true which logically compels or supports an allegation that is made “upon information and belief,” such an allegation is merely a conclusory assertion that should not be deemed to be true by the court on a motion to dismiss. *See Twombly*, 127 S. Ct. at 1962-1963, and 1970 (affirming district court’s ruling that plaintiffs’ allegation, which was made upon information and belief, that the defendants entered into a contract, combination or conspiracy to prevent competitive entry in markets, was merely a conclusory assertion because the factual allegations of parallel conduct, as opposed to independent allegations of actual agreement among the defendants, did not compel or support the conclusion that the defendants entered into a conspiracy agreement).³

The conclusions in the complaint that Alaunus was engaged in the production and/or distribution of MAP and that Alaunus manufactured or distributed contaminated MAP into the stream of commerce are not supported by sufficient factual allegations to support those conclusions. Aside from those conclusions and the allegations that Alaunus shared common officers and managers with NECC and Ameridose, all of the other factual allegations regarding Alaunus are made *upon information and belief*.⁴ Significantly, the complaint does not allege that

³ *See also Szabo Food Service, Inc. v. Canteen Corp.*, 823 F.2d 1073, 1083 (7th Cir. 1987) (“it is not permissible to file suit and use discovery as the sole means of finding out whether you have a case. Discovery fills in the details, but you must have the outline of a claim at the beginning”).

⁴ Again the allegations which are made *upon information and belief* include the allegation that Alaunus shared facilities and/or employees and/or pharmacists in the manufacture, sale, and distribution of various

the FDA recalled any products manufactured or distributed by Alaunus or that Greenspring Surgery Center notified Mr. Martin that he was exposed to contaminated MAP that was manufactured or sold by Alaunus. Even assuming for the purposes of a motion to dismiss that Alaunus had the same registered agent for service of process as and shared common officers and managers with NECC and Ameridose, such facts do not logically compel or even support any of the allegations in the complaint that are made “upon information and belief,” let alone the conclusions that Alaunus was engaged in the sale and distribution of MAP, that Alaunus distributed contaminated MAP into the stream of commerce, or that Mr. Martin’s injection contained MAP that was manufactured or distributed by Alaunus. Consequently, all of the allegations which are made “upon information and belief,” as well as conclusions that Alaunus was engaged in the manufacture, sale and distribution of MAP, that Alaunus distributed contaminated MAP into the stream of commerce, and that Mr. Martin’s injection contained contaminated MAP that was manufactured or distributed by Alaunus, are all conclusory assertions masquerading as factual allegations which should not be taken as true on a motion to dismiss. *See Twombly*, 127 S. Ct. at 1962-1963, and 1970; *The Dartmouth Review*, 889 F.2d at 16.

- b. The fact that Alaunus shared the same registered agent for service of process and the same officers and managers as NECC and Ameridose does not permit a reasonable inference that Alaunus is liable under any of the theories of liability asserted in the complaint.

The complaint predicates the plaintiff’s manufacturing defect claim under theories of negligence, breach of express warranty, and breach of implied warranties of merchantability and fitness for a particular purpose. Putting aside the conclusory assertions in the complaint, the

pharmaceutical compounds with NECC and Ameridose, and Alaunus, *Compl.* ¶¶ 11, 12, that Alaunus jointly participated with NECC and Ameridose in the development, sale, marketing and distribution of compounded medications and products throughout the United States, *Compl.* ¶ 13, that Alaunus supplied NECC with various components of compounded medications for use and sale in compounded products, *Compl.* ¶14, and that Alaunus actively supported and supervised NECC in its business activities including the compounding, manufacturing, selling and distributing of MAP, *Compl.* ¶¶ 14, 15.

pleading fails to state a plausible right to recovery under any of those theories of recovery.

i. Negligence

As part of the causation requirement, a plaintiff suing a manufacturer for negligence in a product-liability action must prove that his or her injury can be traced to that specific manufacturer. *Welch v. Keene Corp.*, 31 Mass. App. Ct. 157 (1991); *Mathers v. Midland-Ross Corp.*, 403 Mass. 688 (1989); *Carrier v. Riddell, Inc.*, 721 F.2d 867, 869-870 (1st Cir.1983) (applying Massachusetts law); *Smith v. Ariens Co.*, 375 Mass. 620, 623 (1978). Additionally, the plaintiff must show “that it is more likely than not that the conduct of the defendant was a substantial factor in bringing about the harm.” *Welch*, 31 Mass. App. Ct. at 162 (quoting Restatement (Second) of Torts § 433B(1) cmt. a (1965)).

Plaintiffs’ complaint fails to assert a plausible claim for negligence against Alaunus because the factual allegations in the complaint do not permit the Court to infer anything more than a possibility that Mr. Martin’s alleged injury can be traced to Alaunus or that that it is more likely than not that the conduct of Alaunus was a substantial factor in bringing about the harm to Mr. Martin. As established above, the only factual allegations that are fairly plead against Alaunus is that it shares common control and management with NECC and Ameridose. However, the complaint does not allege sufficient factual allegations (as opposed to conclusory assertions) to show that Alaunus designed, manufactured, marketed, advertised, or distributed contaminated MAP or that Mr. Martin suffered an injury as a result of contaminated MAP that was designed, manufactured, marketed, advertised, or distributed by Alaunus. Consequently, the negligence claim against Alaunus should be dismissed for failure to state a plausible claim for relief, pursuant to *Twombly* and *Iqbal*, because the assertion in the complaint that Mr. Martin’s injuries can be traced to Alaunus or that that it is more likely than not that the conduct of Alaunus was a substantial factor in bringing about the harm to Mr. Martin is based upon nothing more than conjecture and speculation. *See Patterson v. Novartis Pharmaceuticals Corp.*, 451 Fed. Appx. 495

(6th Cir. Aug. 23, 2011) (holding that district court properly granted defendant's motion to dismiss under *Twombly-Iqbal* because Massachusetts law requires that a plaintiff suing a manufacturer in a product-liability action be able to prove that his or her injury can be traced to that specific manufacturer and the factual allegations in the complaint only permitted the Court to infer the possibility that the plaintiff received infusions of the name-brand drug, Aredia, manufactured by Novartis, as opposed to the generic equivalent manufactured by some other manufacturer); *Funk v. Stryker Corp.*, 631 F.3d 777 (5th Cir. Jan. 25, 2011) (affirming dismissal of manufacturing defect claim concerning medical device under *Twombly-Iqbal* because plaintiffs failed to plead, among other things, the causal connection between the violation and the plaintiff).⁵

ii. Breach of Express Warranty

The express warranty claim should be dismissed for failure to state a claim for relief because the complaint pleads insufficient facts to show that an express warranty was created by Alaunus, that Mr. Martin relied on any such express warranty, and that Mr. Martin suffered an injury as a result of Alaunus' breach of such a warranty.

It is well-settled that in order to recover for breach of an express warranty under Section 2-313 of the UCC,⁶ the plaintiff must show an affirmation of fact or promise made by the seller to the buyer and that the affirmation of fact or promise was made under such circumstances as to warrant the inference that it related to the goods. *O'Connell v. Kennedy*, 328 Mass. 90 (1951);

⁵ See also *Henderson v. Sun Pharmaceuticals Industries, Ltd.*, 809 F. Supp.2d 1373 (N.D. Ga. Aug. 22, 2011) (all claims dismissed under *Twombly-Iqbal* due, in relevant part, to failure to allege sufficient factual allegations to identify the defendant that manufactured the product); *Singleton v. Eli Lilly Co.*, 2011 WL 2621067 (E.D. Cal. June 29, 2011) (all claims in prescription drug case dismissed under *Twombly-Iqbal* due to failure to allege sufficient factual allegations to identify the product's manufacturer); *McFarland v. APP Pharmaceuticals, LLC*, 2011 WL 2413797 (W.D. Wash. June 13, 2011) (all claims in prescription drug/medical device case dismissed under *Twombly-Iqbal* due to failure to identify the product's manufacturer).

⁶ In Massachusetts, the creation of express warranties is governed by M.G.L. c. 106 § 2–313, which provides, in relevant part, that (a) any affirmation of fact or promise made by the seller to the buyer which relates to the goods and becomes part of the basis of the bargain creates an express warranty that the goods shall conform to the affirmation or promise; and, (b) any description of the goods which is made part of the basis of the bargain creates an express warranty that the goods shall conform to the description.

Leavitt v. Fiberloid Co., 196 Mass. 440, 445 (1907). The Plaintiffs' complaint baldly concludes that NECC, Ameridose and/or Alaunus “expressly warranted and represented to members of the public, including Mr. Martin and all other persons similarly situated that its Methylprednisone Acetate was safe, free of defects and reasonably fit for its intended uses” and that such express warranty was made in “its statements, advertisements, promotions, marketing, product brochures and product information.” Given that the complaint does not plead any facts, as opposed to conclusory assertions, regarding the specific affirmation of fact or promise that was made by Alaunus to Mr. Martin or otherwise identify any of the specific materials which were supposedly sent by Alaunus to Mr. Martin, the express warranty claim should be dismissed for failure to state a claim pursuant to *Twombly* and *Iqbal*. See *Johnson v. Brown & Williamson Tobacco Corp.*, 122 F. Supp. 2d 194, 206 (D. Mass. 2000) (dismissing express warranty claim for failure to sufficiently plead facts showing the existence of an express warranty where plaintiff claimed that the defendant extended an express warranty to the decedent through its “advertising, marketing and other efforts,” but offered no specific affirmation of fact or promise, nor any particular description, sample or model that might give rise to such a warranty); *Varney v. R.J. Reynolds Tobacco Co.*, 118 F.Supp.2d 63, 70 (D.Mass.2000) (dismissal of express warranty claim appropriate where plaintiff at no point pleads “the existence of anything remotely resembling an express warranty”).⁷

It is also well-settled that the affirmation of fact or promise by the seller must have become

⁷ See also *Heisner v. Genzyme Corp.*, 2008 WL 2940811 (N.D. Ill. July 25, 2008) (express warranty claim in medical device case dismissed under *Twombly* due to plaintiff's failure to specify the language that constituted the warranty since complaint did not allege any particular affirmation, promise, description, or sample that formed part of the basis of his bargain with defendant); *Simmons v. Stryker Corp.*, (D. N.J. 2008) (express warranty claim dismissed under *Twombly* due to plaintiff's failure to specify the language that constituted the warranty and the source material containing the alleged warranty); *Pennsylvania Employees Benefit Trust Fund v. Astrazeneca Pharmaceuticals LP*, 2009 WL 2231686 (M.D. Fla. July 20, 2009) (express warranty claims dismissed under *Twombly* due to failure to plead any facts supporting direct communication between plaintiff and defendant); *Wendell v. Johnson & Johnson*, 2010 WL 271423 (N.D. Cal. Jan. 20, 2010) (where complaint alleged that defendants “warranted” that the products were “safe, effective, fit and proper for their intended use,” and that the products “were not safe and were unfit” for their intended uses,” court dismissed express and implied warranty claims because plaintiffs failed to allege the contents of any specific warranty or the breach thereof).

part of the "basis of the bargain" in order for the buyer to recover for breach of an express warranty. *O'Connell v. Kennedy*, 328 Mass. 90 (1951); *Leavitt v. Fiberloid Co.*, 196 Mass. 440, 445 (1907). Although there is a split of authority on this issue in various jurisdictions, the district court and superior court in Massachusetts has held that an express warranty only becomes part of the "basis of the bargain" where the buyer relied on the seller's affirmation of fact or promise in making the purchase or using the product. *Stuto v. Corning Glass Works*, Prod.Liab.Rep. (CCH) P 12,585, 1990 WL 105615 (D. Mass. 1990) (Wolf, C.J.); *DiRamio v. Crosby*, Civil No. 03–4872 (Mass. Super. Ct. July 18, 2007) (Botsford, J.); *Fahey v. R.J. Reynolds Tobacco Co.*, Civil No 92–7221, 1995 WL 809837, (Mass. Super. Ct. 1995) (Borenstein, J.); *Hiller v. DaimlerChrysler Corp.*, 23 Mass.L.Rptr. 202, 2007 WL 3260199 (Mass. Super. 2007) (Henry, J.); *Carter v. Scubapro*, 2011 WL 3107334 (D. Mass. 2011) (Gertner, J.) (order adopting and affirming report and recommendation of magistrate). Whereas the complaint fails to plead any facts showing that Mr. Martin relied on any affirmation of fact or promise made by Alaunus, the complaint fails to state a plausible claim for breach of express warranty. *See Stuto, supra*, 1990 WL 105615, * 5 (granting summary judgment to defendant on express warranty claim because some minimum of reliance is a required element of a breach of express warranty claim in Massachusetts and the record clearly demonstrated that plaintiff could not have relied on the express warranty that she claimed were created in defendant's advertisements); *Carter, supra*, 2011 WL 3107334, * 4 (granting summary judgment to defendant on express warranty claim because plaintiff offered no evidence whatsoever of reliance upon or even knowledge of any express warranty).⁸

⁸ See also *Hagenbuch v. Snap-On Tools Corp.*, 339 F.Supp. 676, 10 U.C.C. Rep. Serv. 1005 (D.N.H. 1972) (no warranty created in a sale of a hammer since the buyer did not rely on the statements contained in the seller's catalogue); *Thomas v. Amway Corp.*, 488 A.2d 716, 40 U.C.C. Rep. Serv. 836 (R.I. 1985) (no express warranty in a sale of liquid soap since the buyer did not rely on the statements on the label); *Speed Fastener, Inc. v. Newsom*, 382 F.2d 395, 4 U.C.C. Rep. Serv. 681 (10th Cir. 1967) (in a sale of stud fasteners no express warranty was created because the buyer did not rely on promises or descriptions in the seller's pamphlet); *Hobco, Inc. v. Tallahassee Associated*, 807 F.2d 1529, 1533 (11th Cir. 1987) (stating that "[e]xpress warranty may arise only where justifiable reliance upon assertions or affirmations is part of the

Moreover, since an action for breach of express warranty is an action of contract, *Anthony's Pier Four, Inc. v. Crandall Dry Dock Engrs., Inc.*, 396 Mass. 818, 822 (1986), *Clevenger v. Haling*, 379 Mass. 154 (1979), *Sullivan v. O'Connor*, 363 Mass. 579, 581-582 (1973), the plaintiff must also show that the goods failed to comply with the affirmation or promise and that the failure to comply was the proximate cause of the injury to the buyer to recover on a claim for breach of express warranty, *Lindemann v. Eli Lilly & Co.*, 816 F.2d 199, 4 U.C.C. Rep. Serv. 2d 395 (5th Cir. 1987); *Eddington v. Dick*, 87 Misc.2d 793, 386 N.Y.2d 180 (1976). Given that the complaint fails to plead any facts (as opposed to conclusory assertions) that Alaunus manufactured or distributed MAP into the stream of commerce or that the allegedly contaminated MAP injection was manufactured or distributed by Alaunus, the complaint fails to plead a plausible claim for breach of express warranty. *See Pennsylvania Employees Benefit Trust Fund v. Astrazeneca Pharmaceuticals LP*, 2009 WL 2231686 (M.D. Fla. July 20, 2009) (express warranty claims dismissed under *Twombly-Iqbal* due to failure, in relevant part, to plead any facts in drug case showing proximate cause between breach of warranty and plaintiffs' alleged injuries).

iii. Breach of Implied Warranty of Merchantability

Under M.G.L. c. 106, § 2-314(2)(c), a seller impliedly warrants that a product is "fit for the ordinary purposes for which such goods are used." To establish a breach of implied warranty of merchantability claim, the plaintiff must allege and prove that: (1) the defendant was a merchant, *Ferragamo v. MBTA*, 395 Mass. 581, 586 (1985); (2) the product was sold or leased, *Mason v. Gen. Motors Corp.*, 397 Mass. 183, 189 (1986); (3) the plaintiff's use of the product was foreseeable, *Allen v. Chance Mfg. Co.*, 398 Mass. 32, 34 (1986); (4) the product was defective,

basis of the bargain"); *Horsmon v. Zimmer Holdings, Inc.*, 2011 WL 5509420 (W.D. Pa. Nov. 10, 2011) (express warranty claim dismissed under *Twombly-Iqbal* due to failure to plead the specifics regarding the alleged warranty or how it became part of the basis of the bargain); *Deese v. Immunex Corp.*, 2012 WL 463722 (S.D. Miss. Feb. 13, 2012) (express warranty claims in prescription drug case dismissed for failure to state a claim under *Twombly-Iqbal* due to failure to plead the warranty or how it became part of the basis of the bargain).

Correia v. Firestone Tire & Rubber Co., 388 Mass. 342, 355 (1983); and, (5) the defect was a proximate cause of the plaintiff's injury, *Swartz v. Gen. Motors Corp.*, 375 Mass. 628, 633 (1978), *Barry v. Stop & Shop Co.*, 24 Mass. App. Ct. 224 (1987).

The complaint fails to state a claim for breach of implied warranty of merchantability. The claim is not plausible because, other than conclusory assertions, the complaint does not allege sufficient facts to show that Alaunus was a merchant of MAP who deals in goods of the kind or otherwise held itself out as having knowledge or skill peculiar to the goods involved in the transaction. *See Ferragamo v. MBTA*, 395 Mass. 581, 586 (1985) (holding that MBTA was merchant of used trolley cars because it was highly experienced and knowledgeable with respect to the goods involved, had a long-term and thorough acquaintance with the cars sold to the plaintiff, had contributed to the manufacture of the cars, and had operated, repaired, refurbished, and maintained them for twenty-five years). Additionally, the breach of implied warranty of merchantability claim is not plausible for the same reason as the negligence claim: there are no factual allegations beyond conclusory assertions that Alaunus distributed any contaminated MAP into the stream of commerce or that Mr. Martin's alleged injuries were caused by contaminated MAP that was manufactured or distributed by Alaunus.⁹

⁹ See footnote 5 above. *See also Johnson v. Moog, Inc.*, 2011 WL 719600 (E.D. Tex. Feb. 22, 2011) (all claims in medical device case dismissed under *Twombly-Iqbal* because the pleading asserted only that unknown "defendants" committed actions and failed to state sufficient facts to identify defective product); *Rojas v. Qualitest Pharmaceuticals Inc.*, 2011 WL 334671 (E.D. La. Jan. 28, 2011) (all claims in prescription drug case dismissed under *Twombly-Iqbal* due to failure to plead product identification); *In re Fosamax Products Liability Litigation*, 2010 WL 1654156 (S.D.N.Y. April 9, 2010) (all product liability claims in drug case dismissed under *Twombly-Iqbal* due to failure to plead facts concerning product identification); *Mitchell v. Proctor & Gamble*, 2010 WL 728222 (S.D. Ohio March 1, 2010) (all product liability claims in drug case dismissed under *Twombly-Iqbal* due to failure to plead causation); *Currier v. Stryker Corp.*, 2011 WL 4898501 (E.D. Cal. Oct. 13, 2011) (implied warranty claim dismissed under *Twombly-Iqbal* due to vague allegations concerning "defendants"); *Adams v. I-Flow Corp.*, No. CV09-09550, 2010 WL 1339948, at *3 (C.D. Cal. Mar. 30, 2010) (dismissing products liability claims because complaint did not allege that any particular plaintiff was administered a particular drug through a particular pain pump that was manufactured by a particular defendant; plaintiffs plead nothing more than the sheer possibility that any particular defendant might have manufactured the product that allegedly injured each plaintiff).

iv. Implied Warranty of Fitness for a Particular Purpose

To state a claim for breach of implied warranty of fitness for a particular purpose under M.G.L. c. 106, § 2-315, the plaintiff must show that 1) the seller had reason to know of the particular purpose for which the buyer required the goods, 2) the seller had reason to know of the buyer's reliance on the seller's skill or judgment in selecting or furnishing suitable goods, and 3) the buyer relied in fact. *Fernandes v. Union Bookbinding Co.*, 400 Mass. 27, 34 (1987). Whereas the complaint fails to assert any facts showing that the medical providers were going to use the MAP injections in any manner other than its ordinary purpose in medicine, Plaintiff's claim of breach of implied warranty of fitness must be dismissed as a matter of law. *See Hannon v. Original Gunite Aquatech Pools, Inc.*, 385 Mass. 813, 821 (1982) (where there was no evidence that the buyer was going to use the pool in question for any purpose other than for what a pool is normally used, no particular purpose existed as required for liability under § 2-315).¹⁰ Moreover, the claim for breach of implied warranty of fitness for a particular purpose should be dismissed for failure to state a claim for relief for the same reasons as the negligence and breach of implied warranty of merchantability claims because there are no factual allegations beyond conclusory assertions that Alaunus distributed any contaminated MAP into the stream of commerce or that Mr. Martin's alleged injuries were caused by Alaunus' product.¹¹

v. Concerted Action, Aiding and Abetting, Joint Venture, and Alter-Ego Liability

In addition to the fact that the amended complaint does not state a claim for direct liability

¹⁰ *See also International Petroleum Servs., Inc. v. S & N Well Serv., Inc.*, 230 Kan. 452, 455-457 (1982) (ruling that when goods are acquired for the ordinary purposes for which such goods are generally used, no implied warranty of fitness for a particular purpose arises); *Grinage v. Mylan Pharmaceuticals, Inc.*, 840 F.Supp.2d 862, 2011 WL 6951962 (D. Md. Dec. 30, 2011) (implied warranty of fitness for particular purpose claim dismissed under *Twombly-Iqbal* due to failure to plead any facts showing that plaintiff's husband had any particular purpose that differed from that of other consumers of the prescription drug or that manufacturer had any knowledge of a particular purpose).

¹¹ *See* footnotes 5 and 9 above.

against Alaunus, the complaint falls far short of pleading a plausible right to recovery on a theory of concerted action, aiding and abetting, joint venture, or alter-ego liability.

As set forth above, the only fairly plead allegation regarding Alaunus is that there was common control and management of Alaunus, Ameridose, and NECC. Common control and management, however, is insufficient as a matter of law for the purpose of showing a plausible claim for concerted action liability. *See Santiago v. Sherwin Williams Co.*, 3 F. 3d 546 (1st Circ. 1993) (affirming dismissal of concerted action claim because, even if there was a common design or plan to market and sell paint notwithstanding medical evidence that lead presented significant risk to children, there was no showing that such marketing plan had any role in causing lead paint to be applied to the walls of her childhood home or otherwise caused injury to plaintiff).

Additionally, common control and management is insufficient to establish aiding and abetting liability. *See Kyte v. Philip Morris, Inc.*, 408 Mass. 162, 167-168 (1990) (no aiding and abetting liability where there was no proof that the defendant cigarette manufacturer gave substantial assistance to a store's sale of cigarettes to minors or knew that the store's conduct constituted a breach of duty to minors purchasing cigarettes).

Moreover, common control and management alone does not establish joint venture liability. *See Payton v. Abbott Labs*, 512 F. Supp. 1031 (D. Mass. 1981) (elements of joint venture liability include an agreement among the parties to associate themselves in a business activity, the sharing in the profits and losses of the venture, joint control of the objectives of the undertaking and of the means of achieving those objectives, and a contribution to the assets of the venture).

Nor is common control and management alone sufficient for the purpose of showing a plausible claim for alter-ego liability. *See My Bread Baking Co. v. Cumberland Farms, Inc.*, 353 Mass. 614 (1968) (alter ego liability requires showing of “active and direct participation by the representatives of one corporation, apparently exercising some form of pervasive control, in the activities of another and there is some fraudulent or injurious consequence of the intercorporate

relationship” or “a confused intermingling of activity of two or more corporations engaged in a common enterprise with substantial disregard of the separate nature of the corporate entities, or serious ambiguity about the manner and capacity in which the various corporations and their respective representatives are acting”); *Resolution Trust Corp. v. Driscoll*, 985 F.2d 44, 48 (1st Cir. 1993) (affirming dismissal of claims against corporate defendant because naked assertion of alter ego liability was not supported by sufficient factual allegations).¹²

2. The amended complaint fails to allege a legally sufficient injury as to Mr. Martin because fear of contracting fungal meningitis or some other disease, in the absence of any physiological indications of such disease, is not an actual injury under applicable products liability law.

It is axiomatic that a plaintiff in a product liability suit must prove that he has suffered an actual injury or damages. *Cannon v. Sears, Roebuck & Co.*, 374 Mass. 739, 742 (1978) (“a negligence action may not be maintained unless one has suffered injury or damage”); *Sullivan v. Old Colony St. Ry.*, 200 Mass. 303, 307-308 (1908) (under our law of negligence, injury and damages are integrally related: there can be no invasion of the rights of another unless legal damage is caused, and for that reason nominal damages cannot be recovered); *Iannacchino v. Ford Motor Co.*, 451 Mass. 623, 634 (2008) (“a claim of breach of warranty requires plaintiffs to show that a defendant's conduct has caused them a loss or injury”). Where a plaintiff seeks emotional distress damages in a negligence action, the plaintiff may not recover emotional distress damages unless such emotional distress was caused by physical injury inflicted by the defendant’s negligent conduct (a so-called parasitic emotion distress claim). *DiGiovanni v. Latimer*, 390 Mass. 265 (1983). See *Barney v. Magenis*, 241 Mass. 268, 273 (1922) (allowing recovery for mental suffering “connected with and growing out of the physical injury”); *Bullard v. Central Vermont Ry.*, 565

¹² See also *United States v. Bestfoods*, 524 U.S. 51, 69 (1998) (overlap in directors or officers among affiliated corporate entities is not unusual, and is widely held to be insufficient to establish alter ego liability alone); *Akzona, Inc. v. E.I. Du Pont de Nemours & Co.*, 607 F. Supp. 227, 237 (D. Del. 1984) (holding that overlapping directors was insufficient to pierce veil); *Scott-Douglas Corp. v. Greyhound Corp.*, 304 A.2d 309, 314 (Del. Super. Ct. 1973) (same).

F.2d 193, 197 (1st Cir.1977) (recovery allowed for “necessary or natural consequence of the physical injury” but not for grief, sorrow or mourning).¹³ While it is true that a plaintiff under certain circumstances may recover the costs of past, present, and future medical expenses incurred in monitoring the plaintiff’s medical condition, even in the absence of physical injury, under Massachusetts law,¹⁴ *Donovan v. Philip Morris USA, Inc.*, 455 Mass. 215, 224, 226 (2009), a plaintiff seeking to recover on a medical monitoring claim must, at the very least, allege and prove a corresponding subcellular change that substantially increased the risk of serious disease, illness, or injury. *Id.* at 226.¹⁵

The amended complaint fails to allege a legally cognizable injury suffered by Mr. Martin. Significantly, the Plaintiffs do not claim that Mr. Martin has suffered any physical injury or that he has been diagnosed with spinal meningitis or any other disease as a result of his MAP injection.

Whereas the complaint does not allege that Mr. Martin suffered emotional distress as the result of

¹³ The courts have distinguished between “parasitic” claims of emotional distress which stem from physical injuries and free-standing negligent and intentional infliction of emotional distress claims. *See Payton v. Abbott Labs*, 386 Mass. 540 (1982). Plaintiffs have not asserted a claim for negligent infliction of emotional distress in this action. Even if they had, they would not be entitled to any recovery for the emotional distress suffered by Mr. Martin because the complaint does not allege that the emotional distress caused him physical harm manifested by objective symptomatology. *See Payton*, 386 Mass. at 555 (holding that increased risk of harm and/or fear of future serious disease from exposure to DES is not sufficient injury to warrant recovery for negligent infliction of emotional distress).

¹⁴ Where federal common law applies, the plaintiff has no right to any recovery for medical monitoring. *See Metro-North Commuter Railroad Co. v. Buckley*, 521 U.S. 424, 441-44 (1997); *Norfolk & Western Railway. Co. v. Ayers*, 538 U.S. 135, 156-57 (2003); *June v. Union Carbide Corp.*, 577 F.3d 1234, 1249-51 (10th Cir. 2009); *In re Hanford Nuclear Reservation Litigation*, 534 F.3d 986, 1009-10 (9th Cir. 2008); *Syms v. Olin Corp.*, 408 F.3d 95, 105 (2d Cir. 2005). To the extent that Maryland law applies, the Plaintiffs likely would have no recovery for medical monitoring because the Maryland Court of Appeals, the state’s highest court, affirmatively decided in 2000 not to decide whether to recognize medical monitoring claims without actual injury in *Philip Morris Inc. v. Angeletti*, 752 A.2d 200, 251 (Md. 2000) and no other Maryland court has embraced medical monitoring claims since *Angeletti*.

¹⁵ To recover on a claim for medical monitoring, the *Donovan* Court ruled that a plaintiff must prove that: (1) the defendant’s negligence (2) caused (3) the plaintiff to become exposed to a hazardous substance that produced, *at least, subcellular changes that substantially increased the risk of serious disease, illness, or injury* (4) for which an effective medical test for reliable early detection exists, (5) and early detection, combined with prompt and effective treatment, will significantly decrease the risk of death or the severity of the disease, illness or injury, and (6) such diagnostic medical examinations are reasonably (and periodically) necessary, conformably with the standard of care, and (7) the present value of the reasonable cost of such tests and care, as of the date of the filing of the complaint. 455 Mass. at 226.

any directly inflicted physical injury from the MAP injection, he is not entitled to any recovery in negligence for emotional distress damages. *See Anderson v. W.R. Grace & Co.*, 628 F.Supp. 1219, 1228-1229 (D. Mass. 1986) (concluding that plaintiffs that had contracted leukemia could recover for emotional distress stemming from physical harm to plaintiffs' immune systems by exposure to contaminated water, while non-leukemic plaintiffs who alleged that they suffered emotional distress "as a result of the knowledge that they ... have consumed hazardous chemicals" were not entitled to any recovery because the emotional distress did not stem from any physical harm caused by the defendants); *Watkins v. Omni Life Science Inc.*, 2010 WL 809820, slip op. (D. Mass. March 9, 2010) (fear of future harm from potential failure of hip implant is not sufficient injury).¹⁶ Moreover, the Plaintiffs are not entitled to any recovery for medical monitoring costs because the complaint does not allege that Mr. Martin has experienced any signs, symptoms, or other subcellular changes which are indicative of spinal meningitis or that otherwise increase the risk of developing spinal meningitis. *See Donovan*, 455 Mass. at 226; *see also Miranda v. Dacruz*, 2009 WL 3515196 (R.I. Super. 2009) (Trial Order) (holding that the plaintiff was not entitled to medical monitoring damages because, "unlike the *Donovan* plaintiffs whose lung tissues exhibited changes that warned of potential cancers, [plaintiff's] kidneys, heart, and nerves do not present any

¹⁶ *See also Mink v University of Chicago*, 460 F. Supp. 713 (N.D. Ill. Mar. 17, 1978) (increased risk and/or fear of future serious disease from exposure to DES is not sufficient injury); *Plummer v. Abbott Laboratories*, 568 F. Supp. 920 (D.R.I. July 1, 1983) (same); *Hagepanos v. Shiley, Inc.*, 846 F.2d 71 (unpublished), 1988 WL 35752 (4th Cir. Apr. 18, 1988) (applying Maryland law) (increased risk/fear of heart valve failure is not sufficient injury to recover under theories of negligence, strict liability, express warranty, and implied warranty); *Walus v. Pfizer, Inc.*, 812 F. Supp. 41 (D.N.J. Jan. 22, 1993) (fear of increased risk of heart valve failure is not sufficient injury); *Mattaliano v. Shiley, Inc.*, 1993 WL 13145778 (D.N.J. Feb. 25, 1993) (same); *Yost v. General Motors Corp.*, 651 F. Supp. 656, 657-58 (D.N.J.1986) (holding that complaint alleging design defect "likely to cause" damage failed to state a claim); *Burk v. Sage Products, Inc.*, 747 F. Supp. 285 (E.D. Pa. Sept. 27, 1990) (fear of AIDS from needlestick was not sufficient injury, without proof of actual exposure); *Wood v. Wyeth-Ayerst Laboratories, Division of American Home Products*, 82 S.W.3d 849 (Ky. Aug. 22, 2002) (increased risk of heart disease from exposure to Fenfluramine not sufficient injury); *Aberbach v. Biomedical Tissue Services, Ltd.*, 854 N.Y.S.2d 143 (N.Y. App. Div. Feb. 26, 2008) ("potential" for infection by bone paste is not sufficient injury); *Mitchell v. Proctor & Gamble*, 2010 WL 728222 (S.D. Ohio March 1, 2010) (mere allegation of increased risk, without allegation of actual causation, of damages is insufficient to plead compensable injury under *Twombly/Iqbal*).

physiological changes indicative of future harm").

3. Mrs. Martin is not entitled to any recovery for loss of consortium since her claim is derived from Mr. Martin's failed claims.

For the reasons previously stated, Mr. Martin has no right to any recovery under negligence or product liability theories. Given that the complaint fails to state a claim for relief as to Mr. Martin, the loss of consortium claim by Mrs. Martin fails as a matter of law since it is derivative of her husband's failed claims because loss of consortium claims are entirely derivative and have no existence apart from a viable claim of the other spouse founded on personal injury. *See Diaz v. Eli Lilly & Co.*, 364 Mass. 153, 167-168 (1973); *Short v. Town of Burlington*, 11 Mass.App.Ct. 909 (1981); *Nodal v. Barrett*, 79 Mass.App.Ct. 1132 (2011) (unpublished), 2011 WL 3115331, * 4.

V. CONCLUSION

In sum, the complaint fails to state a claim for relief upon which relief may be granted against Alaunus because it alleges insufficient factual allegations to show that the defendant manufactured or distributed contaminated MAP into the stream of commerce, and that Mr. Martin's injuries were caused by Alaunus. Additionally, the complaint fails to state a claim for relief because it does not allege a legally compensable injury. Moreover, the loss of consortium claim by Mrs. Martin fails as a matter of law since it is derivative of her husband's failed claims.

The complaint woefully fails to plead a plausible right to recovery under any theory of liability and Mr. Martin's alleged emotion distress is in any event not legally compensable as a matter of law. Accordingly, the Plaintiffs are not entitled to conduct any discovery prior to the disposition of this motion to dismiss. *See Twombly*, 127 S. Ct. at 1966 (where discovery would be massive since the plaintiffs represent a putative class of at least 90 percent of all subscribers to local telephone or high-speed Internet service in the continental United States in an action against America's largest telecommunications firms, Supreme Court rejected the arguments that a plaintiff should be permitted to proceed with discovery and that case management techniques may be used

by defendants to weed out baseless claims in an anti-trust case ruling that one of the main goals of the plausibility standard is the avoidance of unnecessary discovery); *Dura Pharmaceuticals, Inc. v. Broudo*, 125 S.Ct. 1627 (2005) (“something beyond the mere possibility of loss causation must be alleged, lest a plaintiff with ‘a largely groundless claim’ be allowed to ‘take up the time of a number of other people, with the right to do so representing an *in terrorem* increment of the settlement value”).

For these reasons, this Court should dismiss the complaint in its entirety, or at the very least as to Alaunus, pursuant to Fed.R.Civ.P. 12(b)(6).

Dated: January 1, 2013

Respectfully submitted,
Defendant Alaunus Pharmaceutical, LLC
By its Attorneys,

/s/ Ryan Ciporkin

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CERTIFICATE OF SERVICE

I, Ryan Ciporkin, hereby certify that, on this 1st day of January 2013, the documents filed through the ECF system will be sent electronically to the registered participants as identified on the Notice of Electronic Filing (NEF).

/s/ Ryan Ciporkin

Ryan Ciporkin